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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

April 15, 1999

WARNING LETTER

NWE-18-99W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stanley C. Hartell, Owner
Arzol Chemical Company
208 Benton Road
P. O. Box 91
North Haverhill, NH 03774

Dear Mr. Hartell:

During an inspection of your manufacturing facility located in North Haverhill, New Hampshire, conducted on March 23, 24 & 25, 1999, Investigator Garry Stewart of the United States Food & Drug Administration (FDA) documented deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). These deviations cause the silver nitrate applicators manufactured by your firm to be adulterated within the meaning of Section 501(a)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

1. Failure to complete batch records. [21 CFR 211.188]

For example, batch information records have not been completed for at least nine (9) lots of silver nitrate applicators produced since February 24, 1999. These (9) lots include lot #s 030299, 030499, 030699, 030899, 031099, 031299, 031499, 031699, and 031899.

Additionally, batch information records representing at least [redacted] lots of silver nitrate applicators produced between January 5, 1999, and March 1, 1999, lacked calculations of actual vs. theoretical yield. These (23) lots of silver nitrate applicators include lot #s 010299, 010499, 010699, 010899, 011099, 011299, 011499, 011699, 011899, 012099, 012299, 012699, 020299, 020499, 020699, 020899, 021099, 021299, 021599, 021799, 021999, 022299, and 022499.

2. **Failure to test finished product. [21 CFR 211.165]**

For example, there is no evidence that any of [redacted] lots of silver nitrate applicators produced in September, October, or November, 1998, were tested for silver nitrate and potassium nitrate.

3. **Failure to test incoming components. [21 CFR 211.84(d)]**

For example, there is no evidence that either the silver nitrate or potassium nitrate components used in the production of silver nitrate applicators over the past five (5) years were tested for purity, strength and quality; nor is there any evidence that an identity test was conducted on those components which were accompanied by a Certificate of Analysis from the supplier of the components.

4. **Failure to follow written procedures. [21 CFR 211.100(b)]**

For example, your "Production Procedure for Arzol Silver Nitrate Applicators" states that [redacted] is to be added to the silver nitrate and potassium nitrate solution during the production of silver nitrate applicators. However, you informed Investigator Stewart that you rarely add the [redacted] to the solution.

5. **Failure of the production and process control records to assure that drug products have the identity, strength, quality, and purity they purport or are represented to possess. [21 CFR 211.110(a)(3)]**

For example, your "Master Production and Control Report" specifies that each batch of silver nitrate applicators is produced ove[redacted]days. However, this record fails to provide for the re-melting of the silver nitrate and potassium nitrate mixture on the [redacted]

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Alyson L. Saben, Compliance Officer at above address or (781)279-1675 ext. 120.

Sincerely,

John R. Marzilli
District Director
New England District Office